

TRANSLATIONAL RESEARCH

**Medical Research, Development
and Clinical Investigation**

and the

Health Affairs Attachè Initiative

**Wayman W. Cheatham, MD, FACE,
CAPT Richard Haberberger, MSC, CAPT Ben Balough, MC,
CAPT Patricia Kelley, NC**

**Navy Medicine Senior Leadership
Conference**

19 - 22 January, 2011



TRANSLATIONAL RESEARCH

Medical R&D and Clinical Investigation & The Health Affairs Attachè Initiative



Serving DoD, Navy, Marine Corps and Foreign Partnership Needs

Purpose of This Session

- For Navy Medicine leadership at the Echelon 2, 3, 4 and 5 levels to recognize the priority of developing integrated medical R&D and clinical investigation support
- To provide insight in recognizing the gaps that exist in supporting the FHP, Performance Optimization, Injury Intervention, and Return to Fitness
- To provide insight in recognizing the gaps in supporting efficient/effective delivery of advances in medical care at the MTF
- To introduce the concept of facilitating Global Health Diplomacy, and thereby strategic interests in FHP and Capacity Building, via a more readily accepted DoD entree into cooperation with select foreign military and civilian medical activities

ACTIVITY

- Past 2 Years:
 - Implementation of infrastructure to support and to provide oversight of the medical research and clinical investigation products
 - Publication of The Surgeon General's Strategic Medical Research Priorities
 - Assessment of the relative percentage of Navy Medicine research activities that are targeted to support the military mission

ACTIVITY

- Past 2 Years:
 - Development of a common monitoring platform to assess progress in 4 major areas
 1. Production of required research products that preserve, protect, treat, rehabilitate, or enhance the performance of Navy and Marine Corps personnel and health care services
 2. Engagement in partnerships to enhance efficiencies, build capacities and protect Navy Medicine pertinence in the medical research and academic communities World-wide
 3. Achievement and maintenance of a national and international reputation as a high quality high performance biomedical and military medicine research enterprise
 4. Creation of a Common Operating Picture (COP) linking requirements with R&D/CI efforts in all venues - articulating the impact of outcomes on health care services

ACTIVITY

- Past 2 Years:
 - Inauguration of the Executive Research Advisory Board (ERAB) to develop recommended policy and to provide oversight of **ALL** of the Navy Medicine research and clinical investigation assets –
 - guiding investment and utilization of resources
 - targeting effective delivery of products to fill our operational force and beneficiary medical needs

ERAB Membership

- The Navy Surgeon General - Ex Officio
- The Navy Deputy Surgeon General - Ex Officio
- Medical Officer of the Marine Corps and/or Representative
- Fleet Forces Command Surgeon and/or Representative
- CO, Navy Medicine East and/or Representative
- CO, Navy Medicine National Capital Area and/or Representative
- CO, Navy Medicine West and/or Representative
- Director, OPNAV 931
- Director, ONR Force Health Protection
- Special Assistant to The Navy Surgeon General for Medical Research - Chairman
- Special Assistant to The Navy Surgeon General for Ethics
- Special Assistant to The Navy Surgeon General for Human and Animal Protections
- Special Assistant to The Navy Surgeon General for Pastoral Care
- Deputy Director, Navy Medicine Research and Development Center for R&D
- Deputy Director, Navy Medicine Research and Development Center for Clinical Research
- Deputy Director, Navy Medicine Research and Development Center for Nursing and Allied Health Sciences Research
- Uniformed Services University Representative
- (to be added) Director, National Intrepid Center of Excellence

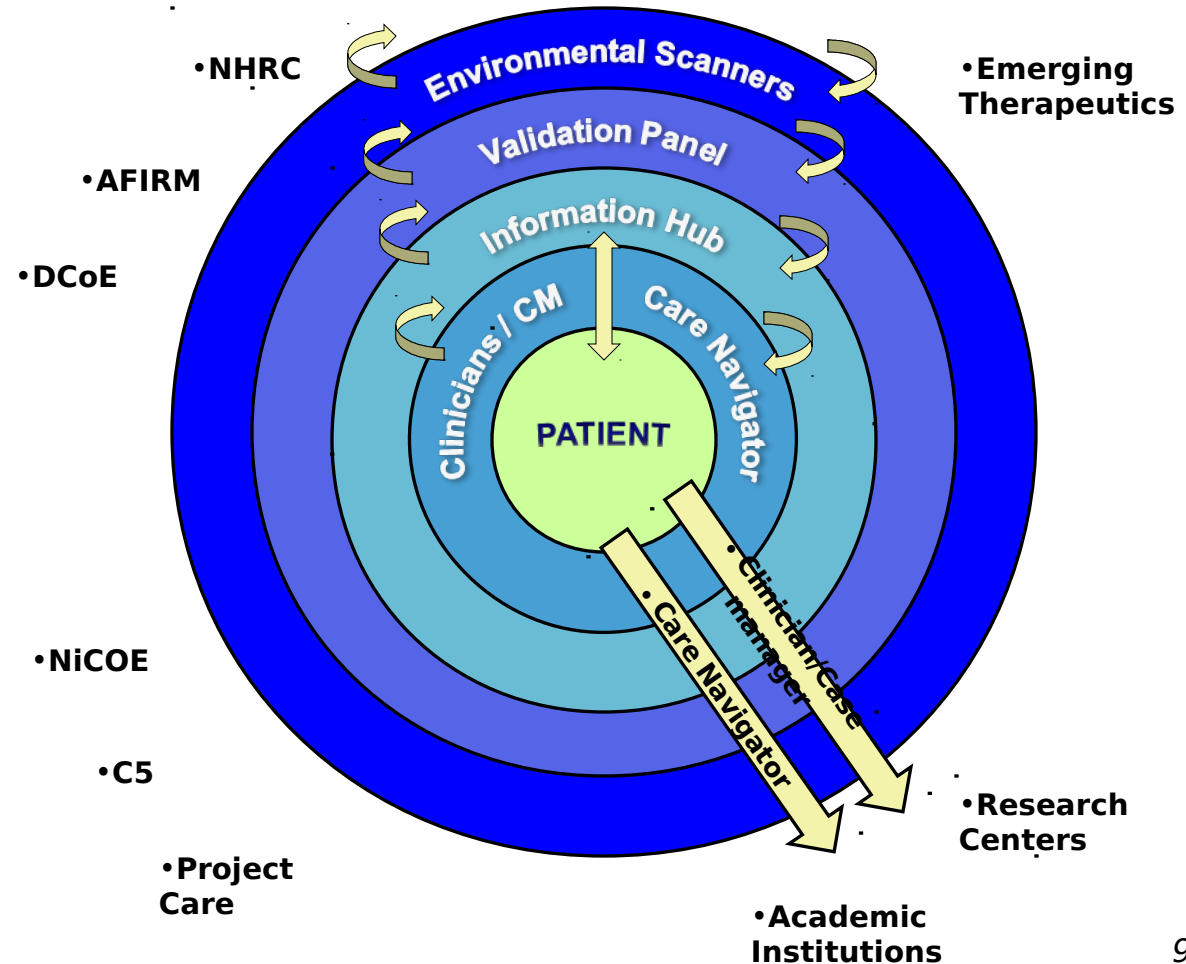
ACTIVITY

- Past 2 Years:
 - Facilitation of the development and initiation of a method and review panel to provide: Environmental Scanning of Emerging Research/Therapeutic Developments and Validation
 - Scanning research and clinical publications
 - Scanning public media
 - Reviewing DoD supported medical R&D
 - Using Navy Medicine SMEs as members of the Validation Panel



Construct of a Possible Solution

Policy Statement: It is Navy Medicine policy to develop and implement processes that connect wounded warriors to approved emerging and advanced diagnostic and therapeutic options within and outside of military medicine while ensuring full compliance with applicable patient safety policies and practices.



ACTIVITY

- Past 2 Years:
 - Facilitation of the emergence of The Navy Surgeon General's Strategic Priority of Institutionalizing the Navy Medicine programs in [Global Health Diplomacy](#)
 - Review and categorizing Navy Medicine Overseas Lab activity under aegis of formal memoranda of agreement/understanding
 - Review and tabulation of topical areas of research activity at Navy Medicine Overseas Labs
 - New relationship development and capacity building activities
 - Vietnam
 - Papua New Guinea

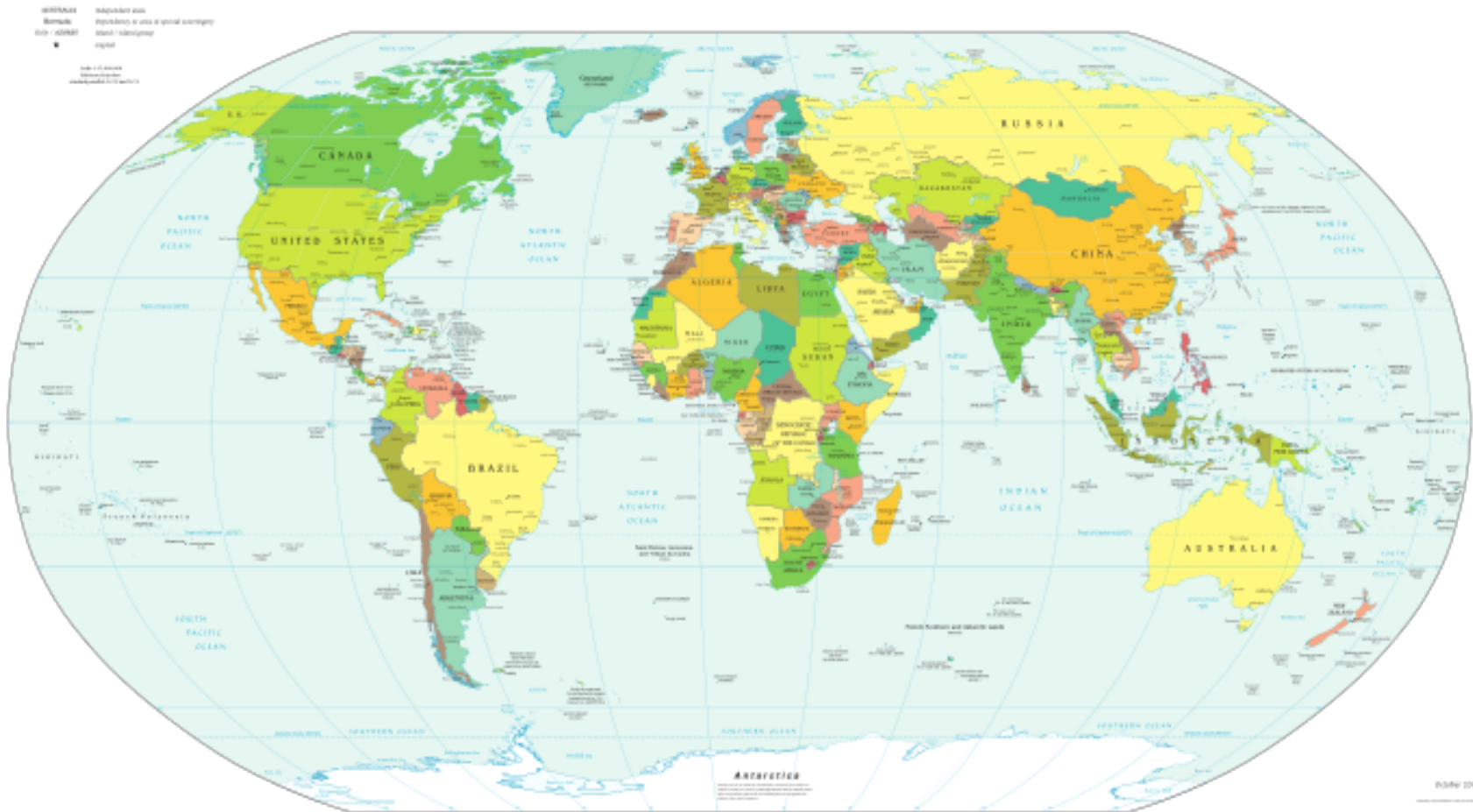


Navy Medicine Support of Global Health Diplomacy via Health Affairs Attachè Billet

- Principal advisor to The U.S. Ambassador for all military and civilian Health related issues and activities involving all U.S. health agencies operating in-country
- Senior U.S. Medical Officer at US Embassy
 - Interacts with and coordinates activities with Vietnamese Medical Officials in the Ministry of Defense, the Ministry of Health and the Ministry of Labor Invalids & Social Affairs
- Serves as liaison for medical research collaboration and scientific exchange programs on behalf of DOD/Navy Medicine
- Provides advice and oversight for DOD PEPFAR/DHAPP activities
- Principal coordinator for all Medical Exercises involving U.S. Military Forces, Medical Civil Action Programs,(MEDCAPS); Humanitarian Activities,(HA); Disaster Relief efforts (DR)

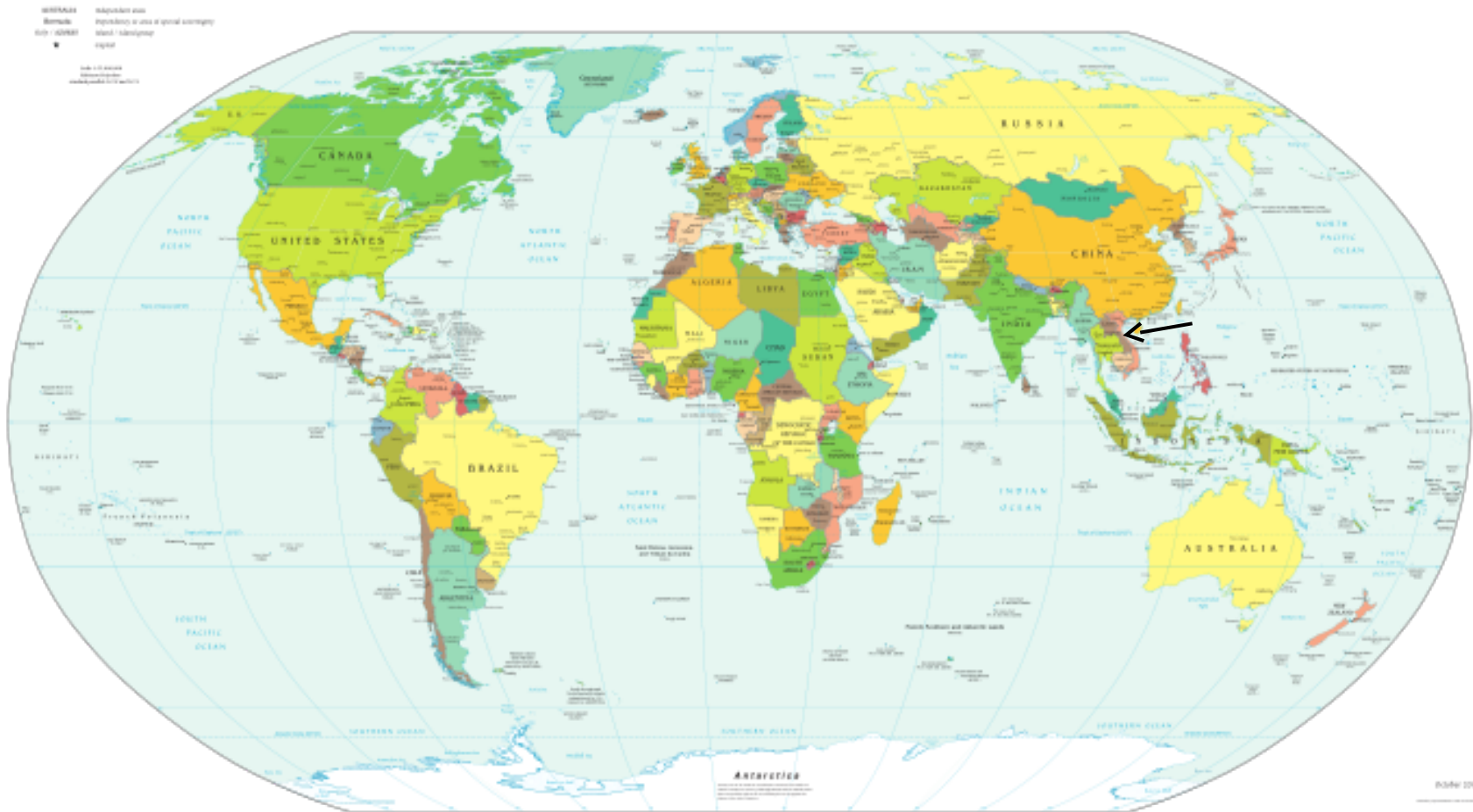
Health Affairs Attachè Initiative

Political Map of the World, October 2010



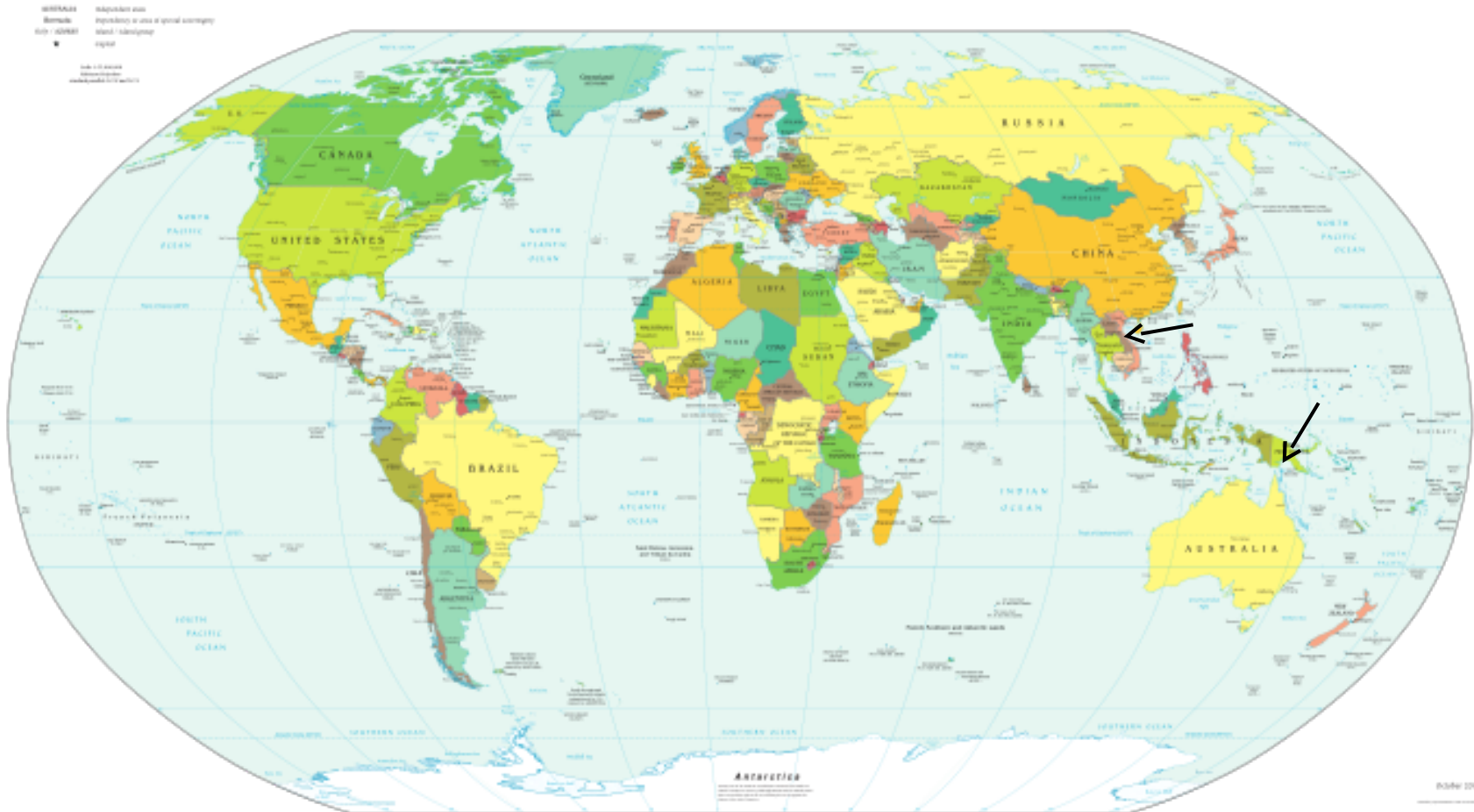
Health Affairs Attachè Initiative

Political Map of the World, October 2010



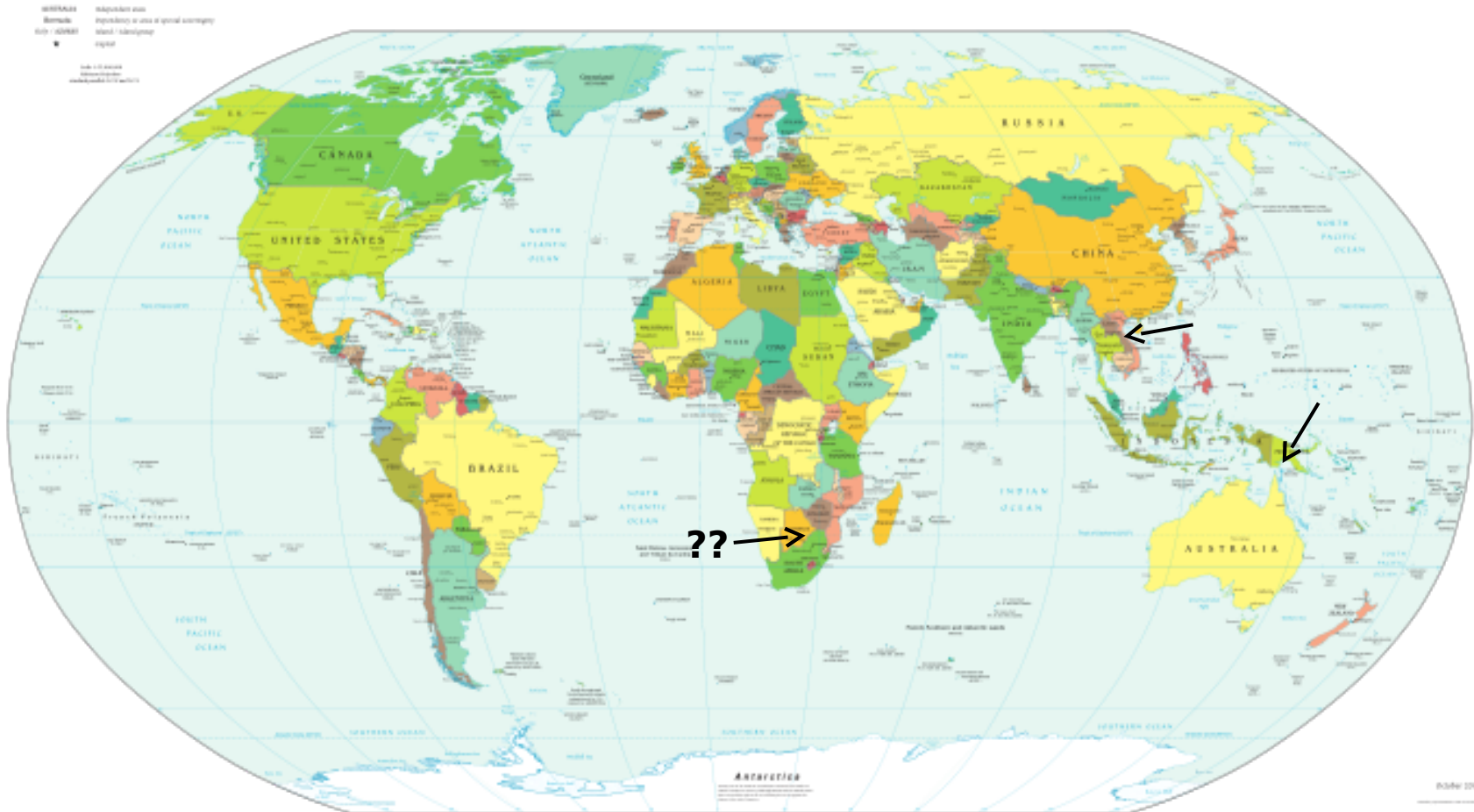
Health Affairs Attachè Initiative

Political Map of the World, October 2010



Health Affairs Attachè Initiative

Political Map of the World, October 2010



Navy Medicine R&D Laboratories

The C2 Enterprise of Naval Medical Research Center

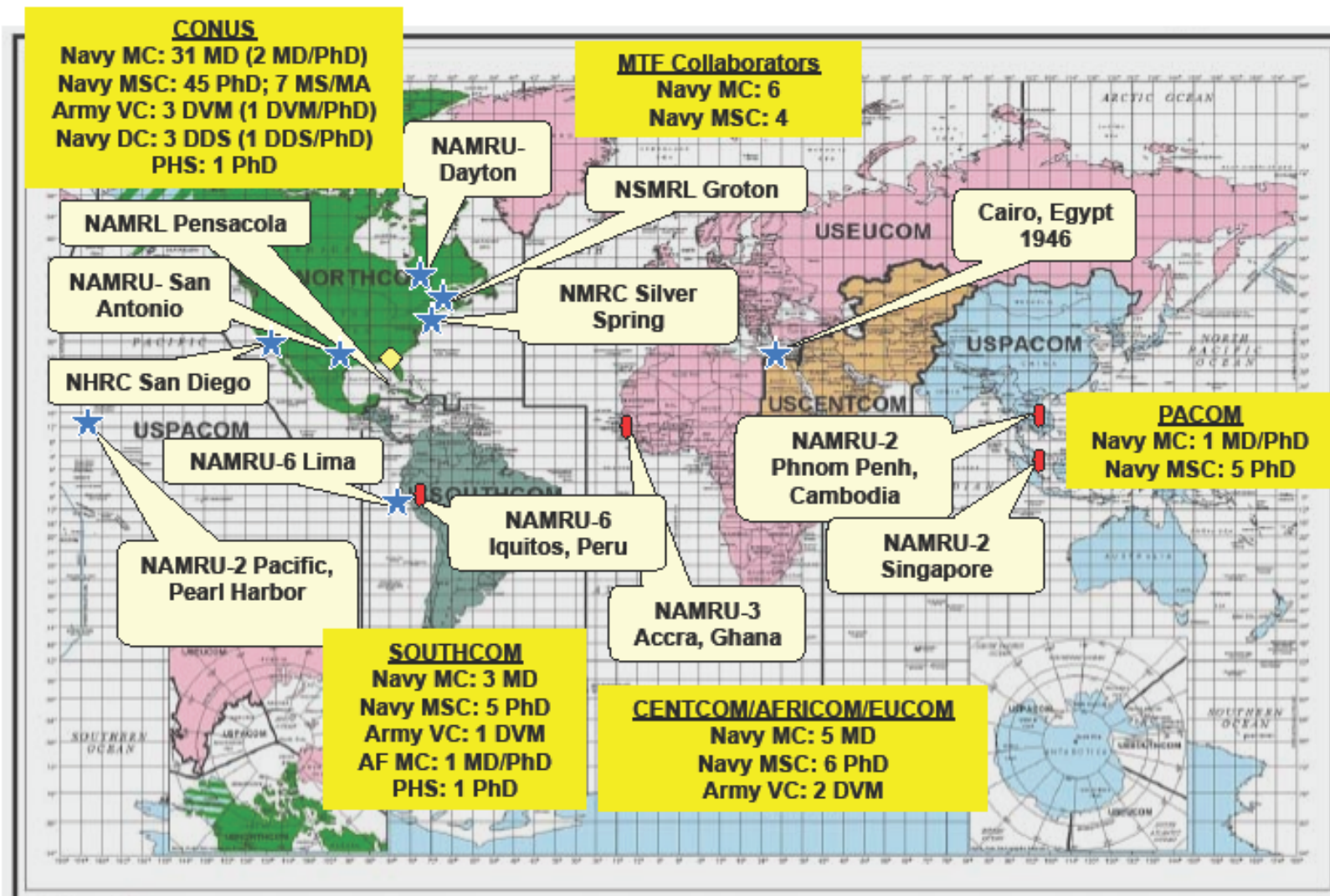


Presentation to The Surgeon General's Senior Leadership Conference

**CAPT Richard Haberberger, MSC, USN
Commanding Officer
Naval Medical Research Center**

20 January 2011

NMRC Commands[★], Dets,[◇] and Field Sites[●]



NAVAL MEDICAL RESEARCH CENTER

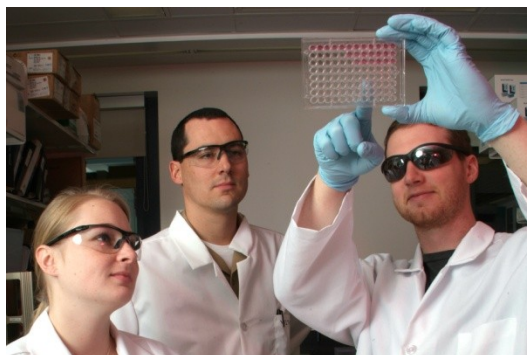
Science Directorates

Operational and Undersea
Medicine

Biological Defense

Infectious Diseases

Bone Marrow Research



NAVAL HEALTH RESEARCH CENTER

Science Departments

Medical Modeling, Simulation, and Mission Support

Warfighter Performance

Behavioral Sciences and
Epidemiology

Deployment Health Research

HIV/AIDS Programs

Respiratory Diseases Research



September 2010



NAVAL SUBMARINE MEDICAL RESEARCH LABORATORY

- Science Capabilities
- Naval diving
- Hyperbaric Medicine
- Occupational Medicine
- Audiology
- Physiology
- Psychology
- Submarine Medicine



September 2010



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NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO

Science Departments

Directed Energy Biomedical Research
Combat Casualty Care Research
Dental and Biomedical Research



September 2010

NAVAL MEDICAL RESEARCH UNIT- DAYTON (NAMRU-DA = NAMRL + EHEL)

- Inhalation Toxicology
- Mechanistic Toxicology; End point discoveries and biomarkers
- Hyperbaric Oxygen; Tx of CO poisoning
- Environmental Toxicology and Threat Detection



NAMRU-3 Cairo Staff and Facilities

- Cairo: 20 AD, 17 GS, 144 LES, 89 contractors
- Ghana: 1 US, 3 LES, 8 contractors
- Afghanistan: 6 contractors
- Contract/sub-contract field site staff located in more than 20 countries

- **26 buildings**
- **3.5 acres**
- **115.4 K sq ft**
 - **42.6 laboratory**
 - **19.3 administration**
 - **53.5 support**
- **2 BSL3s - in parallel**



NAMRU-6 Lima Staff and Facilities



- Staff:
 - 12 Officer
 - 2 Enlisted
 - 2 GS
 - 175 LES/FSN
 - 169 Contractor

- 37,000 sq ft lab and animal facility
 - Laboratories of virology, bacteriology and parasitology
 - Two Biosafety level 3 labs
- AAALAC Certified Animal Facility:
 - ~130 *Aotus* monkeys
 - ~1200 Mice
 - BSL 3 animal lab as well



NAMRU-6 - Lima

Iquitos Laboratory



- **5,000 sq ft on the base of the Clínica Naval Base in Iquitos**
- **Opened in March 2006**



• **Insectary**

Naval Medical Research Unit No. 2 - Pacific



Staff:

15 Personnel

- 5 Officers
- 4 Enlisted
- 5 Civ
- 1 Contractor

Southeast Asia Operations

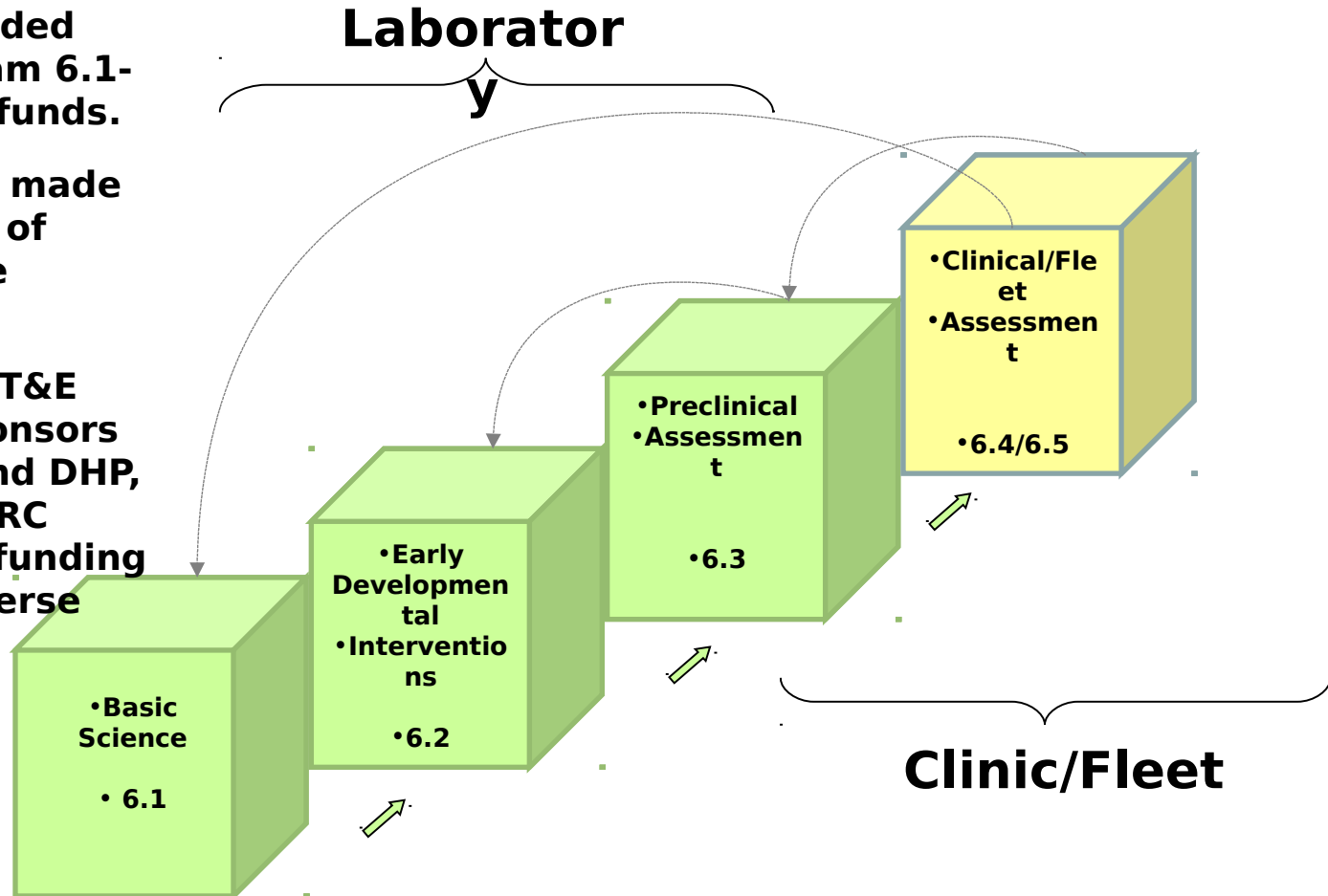
- Phnom Penh, Cambodia: ~2500 ft² at National Institute of Public Health
 - 1 Navy MC Officer
 - Navy MSC microbiologist
 - 7 FSNs
 - 84 contract staff in Phnom Penh and at field sites
 - (US staff to change to 3 MSC Microbiologists & 1 MC Officer
 - Studies focus on febrile illnesses, avian influenza, diarrhea, and malaria
- Singapore: One Navy MSC microbiologist based at US Embassy Singapore
 - (ODC + working with Singapore Defense Forces on infectious diseases of mutual importance)
- Laos: Sentinel Surveillance Net – (operated with Laotian Ministry of Health

Translational Innovation from the NMRC Enterprise - Working Closely with MTFs



“Bench to Bedside” (and back again) Building Blocks

- Studies funded with program 6.1-6.5 RDT&E funds.
- Awards are made in the form of competitive “grants”
- Primary RDT&E funding sponsors are Navy and DHP, but the NMRC Enterprise funding is quite diverse



Medical science progresses forward from basic to advanced. Knowledge from higher levels of medical development inform basic research to continually renew innovation. The DNA based vaccine is an example of this spiral development.

Department of the Navy

Clinical Research within the MTF's

Ben J. Balough, CAPT, MC, USN
Deputy Director, Clinical Research
Naval Medical Research and Development
Center
Bureau of Medicine and Surgery

20 Jan 2011

Medical/Clinical Investigation



Resources

- Over 80 health care disciplines supported
- >1000 staff/trainees engaged with >800 active projects
- \$12 million in P8/P6 funded projects - service showing growth in dollars
 - In comparison to other services:
 - With 1/2 the projects vs. Army
 - With roughly 1/3 the dollars vs. Army
 - With 1/7th the number of support staff vs. Army

MTF Clinical Research Funding

<u>Funding Source</u>	<u>FY08</u>	<u>FY09</u>	<u>FY10</u>
Intramural (O&M/DHP)	\$1,804,615	\$3,843,528	\$3,020,091
Extramural - Other DoD and Federal Gov	\$2,610,672	\$722,990	\$844,761
Extramural - Private	\$4,639,452	\$4,978,023	\$8,461,479 (\$11M)
TOTAL FUNDING 3.4% increase, 430% increase, CIP 1 and 2 Programs begun FY10 ^{1 2} •High degree of variability within regions and funding types reflect pockets of depth and experience but little breadth	\$9,054,379 (\$41.5M)	\$9,544,541 ¹ (\$40M)	\$12,366,331 ² (\$38.6M)

Clinical Investigation Program Accomplishments FY10

The BUMED Strategic Initiative Continues

- **Funding**
 - **CIP1: \$1.3 million for competitive grants**
 - 20 total awards³ , 98% execution rate
 - **CIP2: 1/4 of 1% Regional O&M for CIP⁴**
 - Floor for infrastructure support
- **Alignment**
 - **R&D/CIP Strategic Goals reported to CEB^{5,6}**
 - **Contract Support for MTF's: CRUNCH**
 - **eRPM**
- **Community**
 - **Lansdowne Research Enterprise Meeting -
Furthering of R&D/CIP Synergy**

FY11 - 15 Clinical Investigation Program Goals

- **Research Administration**
 - **Develop NMRDC**
 - **Uniform BUMED Policy/Structure**
 - **Education with Certification**
 - **Stable, networked, professional staff**
- **R&D/CIP Metrics**
 - **Expand and develop**
 - **Automate reporting**
 - **RPM => eRPM**
- **Program Development**
 - **Transition CIP1 “winners”**
 - **Knowledge as well as Product**
- **Community**
 - **Annual Navy Medicine Research Meetings**
 - **ONR/Fleet-USMC/WII Program Relationships**
 - **ERAB Membership**



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State of Dental Research & Development

***CAPT Mark Lyles, DC, USN &
CDR Kenneth Green, DC, USN***

Presented by CAPT Ben Balough, MC, USN

**Navy Surgeon General
Senior Leadership Conference**

**20 January 2011
Alexandria, VA**



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Traumatic Brain Injury and PTSD

- **Orofacial Pain** Research
- **Use of Intranasal CO₂** to Treat Migraines / Headaches
- **Maxillofacial Prosthetics**
- **Cranioplasty** (including use of nanoparticle matrix scaffolding)





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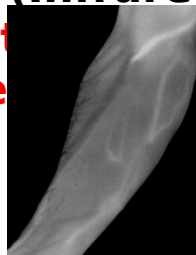
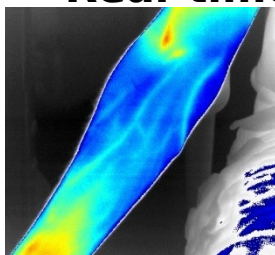


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Medical Systems Support for Maritime and Expeditionary Operations

- **MedicEye**

- Real-time IR (Infrared) battlefield diagnostics - **external**
cont **fra** **ng, head injury,**
sh, e



- **Maxillofacial Reconstruction & Prosthetics**
- **Biomaterials**
- **Preventive dentistry**
- **Tissue engineering, Regenerative medicine**
- **Orofacial pain**
- **Oral/facial infection**



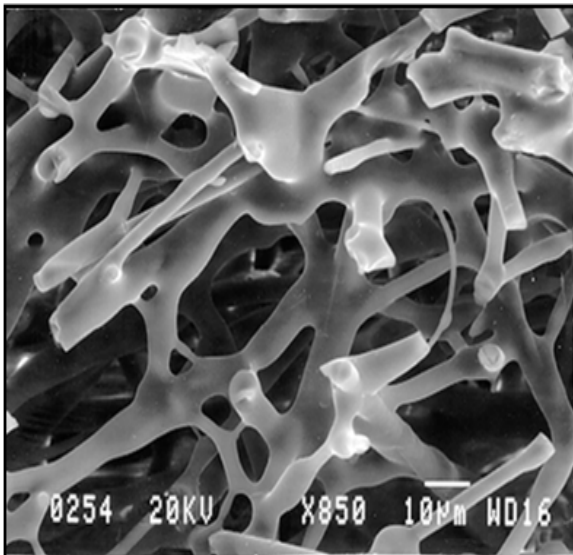
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Wound/Injury Management Throughout the Continuum of Care

- Maxillofacial prosthetics
- Maxillofacial infection management



Ceramic - Metal Bone Matrix Scaffold



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Nursing and Allied Health Sciences Research

***CAPT Patricia W. Kelley, NC, USN
Deputy Director, Nursing and Allied Health Sciences
Research
Navy Medicine Research and Development Center***

**Navy Surgeon General
Senior Leadership Conference**

20 January 2011
Alexandria, VA

01/20/2011

Nursing & Allied Health Sciences Research

Nursing Research

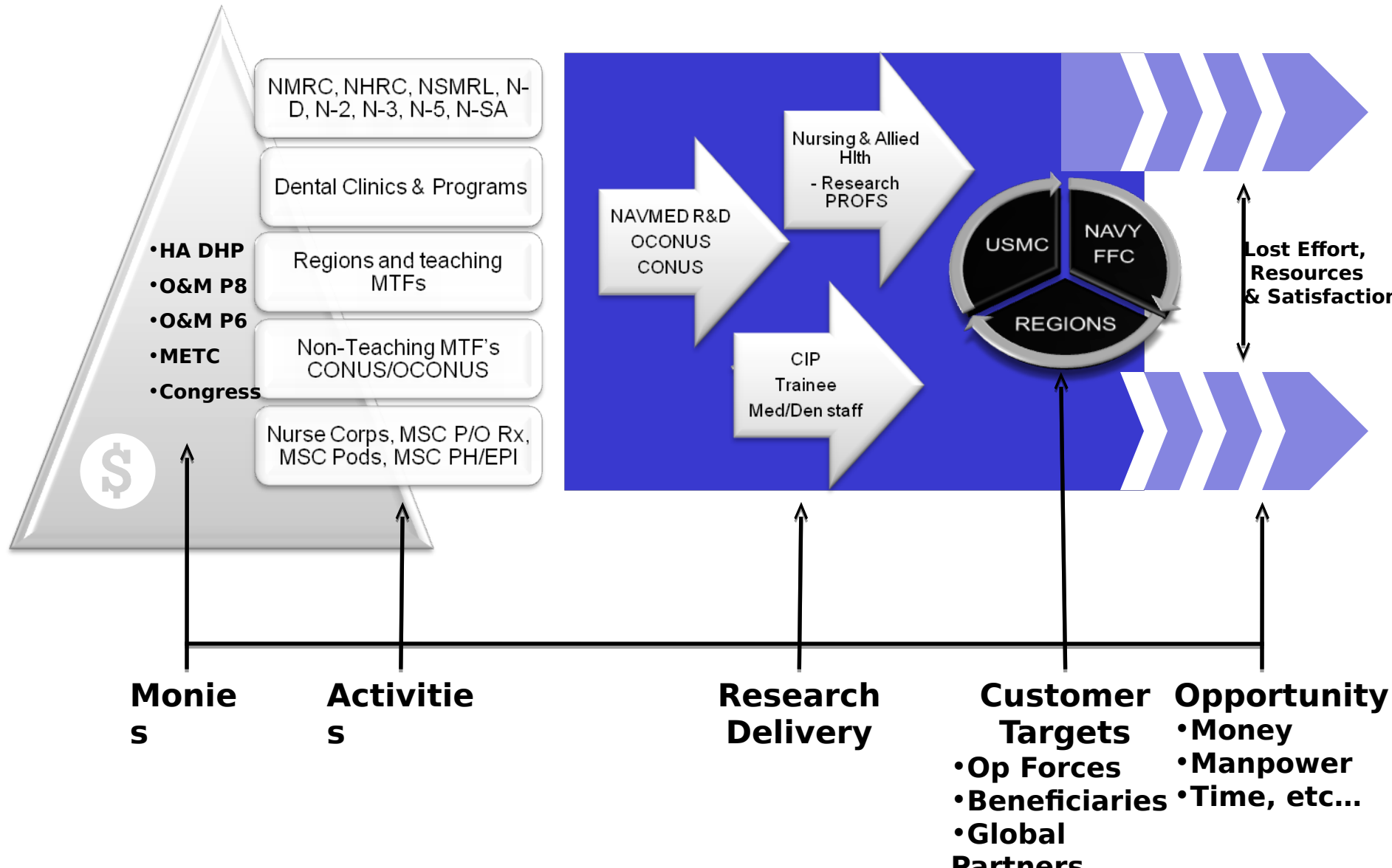
- **MTF based**
 - in patient
 - out patient
- **Most nursing research is investigator initiated**
- **Areas of Investigation**
 - Psychological health and resilience
 - Nursing bedside care competencies
 - Clinical knowledge development continuity of care for the war injured service members'
 - Wound care
 - EBP
 - Pain management and visualization

Nursing & Allied Health Sciences Research

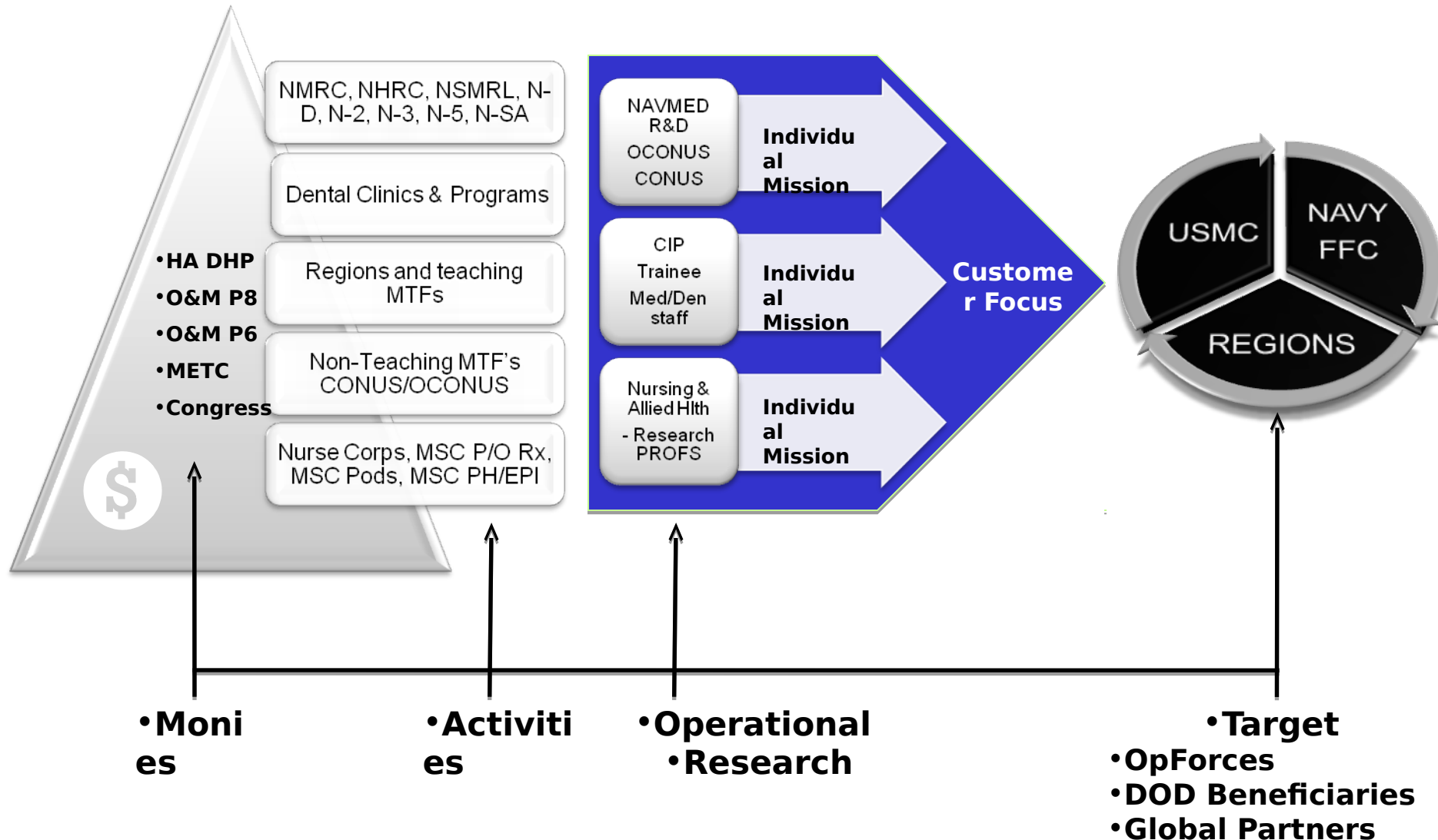
Allied Health Sciences Research

- MTF Based**
 - Physical, Occupational & Speech Therapy**
 - Social service**
 - Psychological**
 - Optometry**
 - Nutrition / Dietetics**
 - Pastoral Care**
 - Podiatry**
 - Pharmacy**
 - Physician's Assistant**
 - Audiology**

Delivery Model



Future Delivery Model





Desired Alignment Goal

CUSTOMERS →

**OUR CUSTOMERS ARE:
OUR OPERATIONAL FORCES
OUR MHS BENEFICIARIES &
OUR GLOBAL PARTNERS**

**OPERATIONAL
RESEARCH PROVIDERS** →

**NAV MED
INSTITUTIONAL
ASSETS** →

SPONSORS →

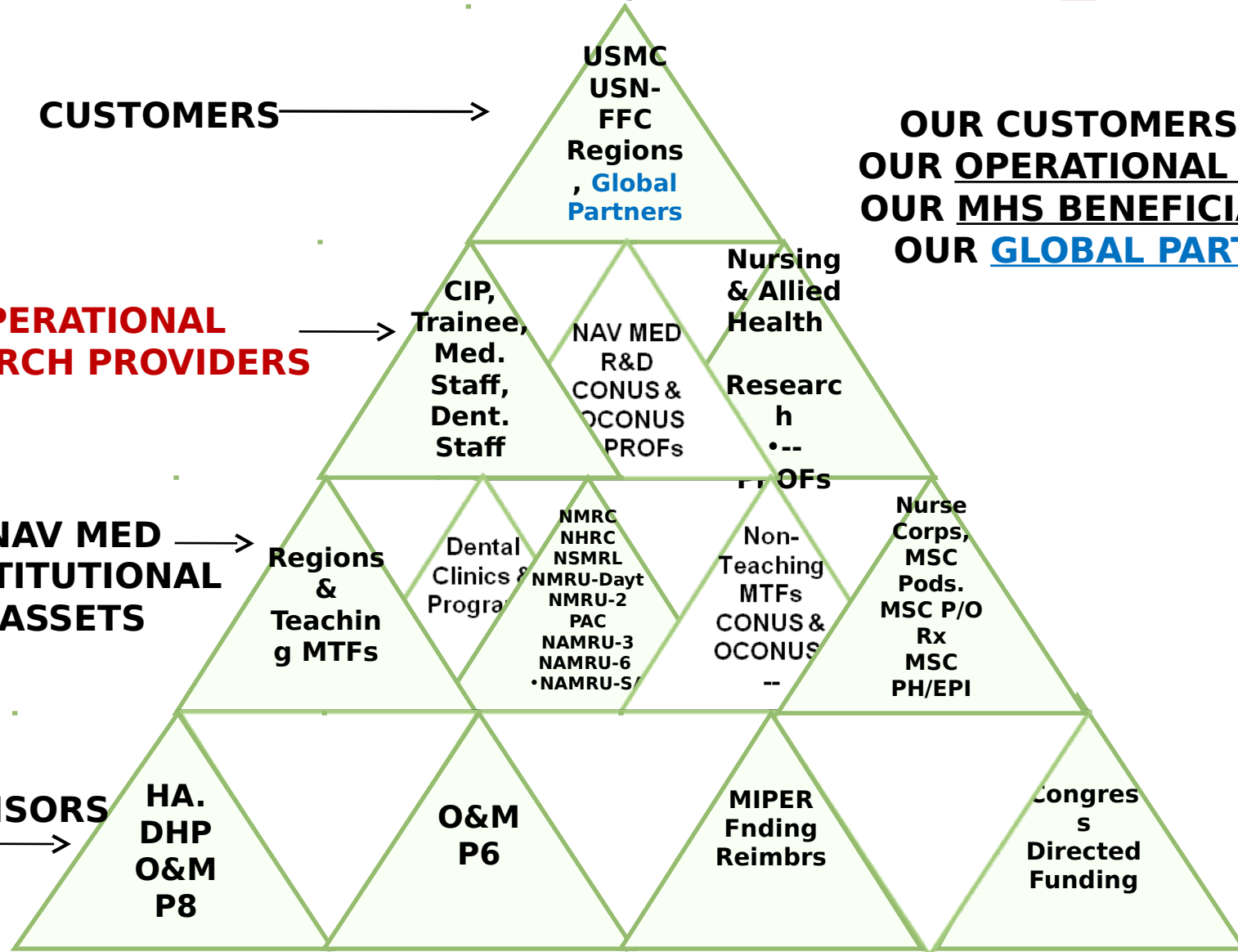


TABLE TOP EXERCISE



1. What research resources do you currently recognize and/or utilize in your command?
2. What research is being conducted in your command that supports our operational forces (both Marine Corps and Fleet Forces) in addressing their specific needs, gaps and your ability to care for the wounded, ill and injured?
3. How do you currently receive information regarding the needs of our operational assets (Marine Corps and Fleet Forces) in terms of products and interventions that your command could undertake as development and translational research projects?
 - A. What do you recommend as a means to improve your ability to receive this information in regard to these needs?
 - B. What do you recommend as a means to expand your ability to foster and support such research?
4. What level of priority do you give to research capacity to support the:
 - Translation of developed knowledge and products from R&D to the O.R., bedside and field
 - GME
 - Nursing activity
 - Dental activity
 - Allied Health Science activity

[Score from 0 to 4, with 4 = Highest, 2 = Mid-level Priority, 0 = No Priority]

Back-Up Slides for Inclusion with Handouts

Naval Medical Research Center Enterprise

Mission

- To conduct health and medical research, development, testing, evaluation, and surveillance to enhance the operational readiness and performance of DoD personnel worldwide

Vision

- World-class, operationally relevant health and medical research solutions – anytime, anywhere!

Navy Medical RDT&E

Enterprise Resources (as of 12/31/10)			
CONUS		OCONUS	
Facilities			
6		6	
Total		12	
Personnel			
94	Officers	32	Officers
19	Enlisted	6	Enlisted
200	CIV & IPAs	336	FSNs & CIV
483	Contractors	324	Contractors
796		698	
Total		1494	

Joint Mission Statement

To identify infectious disease threats of military and public health importance and to develop and evaluate interventions and products to mitigate those threats

• Goals

- Identify & evaluate ID threat agents and insect vectors of infectious diseases
- Define the epidemiology and immunology of militarily relevant ID agents
- Evaluate diagnostic tests, vaccines, drugs & insect control/protection measures
- Establish ID surveillance and response programs in collaboration with national and international health authorities.

• ROI Develop host nation public health lab and epidemiology capacity

- Medical information in support of operational forces
- Engagement with host-national governments reinforcing U.S. foreign policy
- Theater Security Cooperation



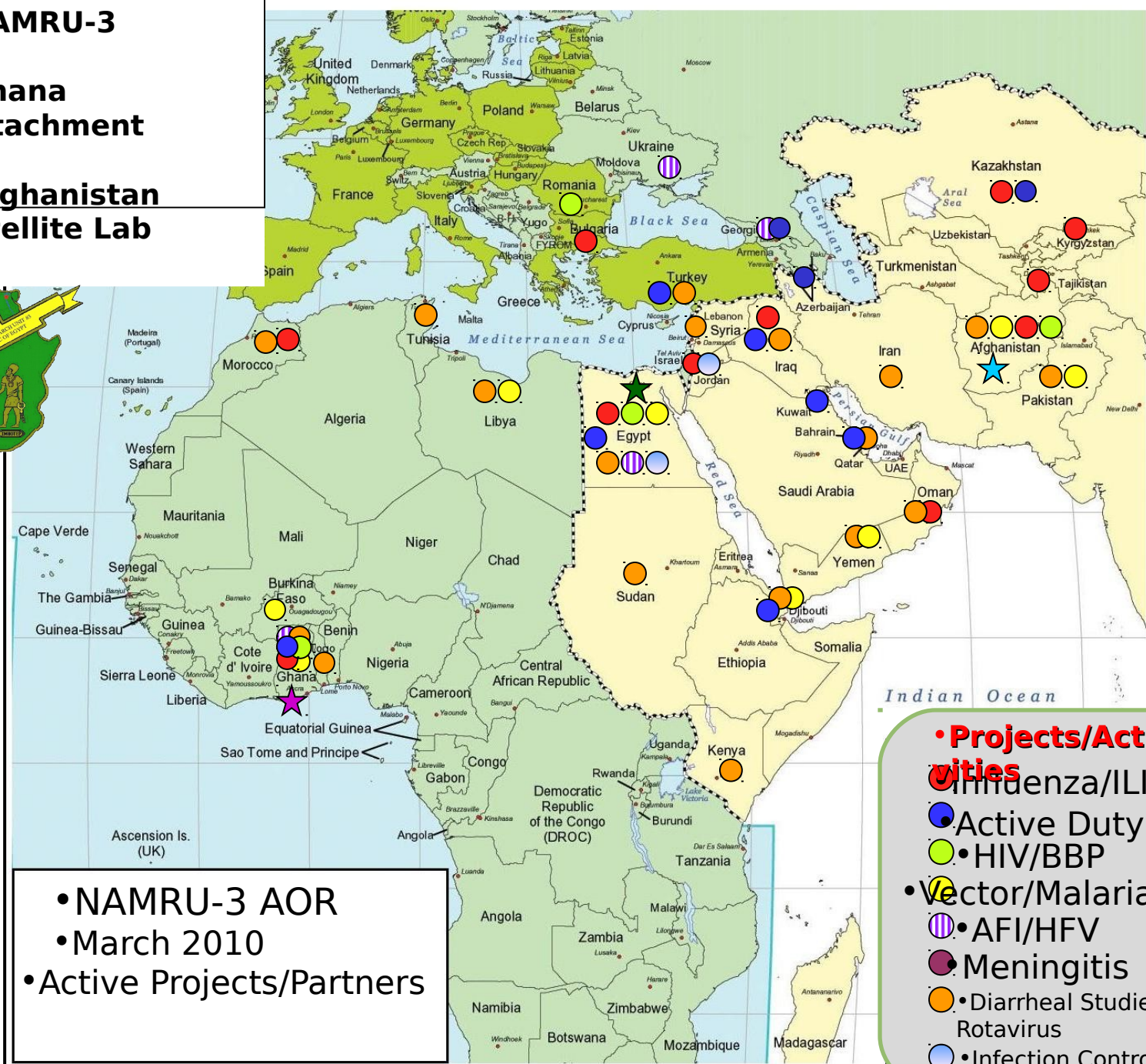
• **NAMRU-3**



• **Ghana Detachment**



• **Afghanistan Satellite Lab**



• **NAMRU-3 AOR**
• **March 2010**
• **Active Projects/Partners**

- Projects/Activities**
- Influenza/ILI
 - Active Duty
 - HIV/BBP
 - Vector/Malarial studies
 - AFI/HFV
 - Meningitis
 - Diarrheal Studies/ Rotavirus
 - Infection Control

• NMRC Active Programs



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- AFI/HFV
- Febrile
- HIV
- Influenza Surveillance
- Influenza Wetlands Project
- Riverine Health Assessment
- Traveler's Health
- Peace Corps
- Epidemiologic Surveillance System (Alerta)
- Control of Dengue vector *Aedes aegypti*
- Determination *Plasmodium vivax* transmission
- Field Evaluation of Candidate repellents for personal protection measures against *Anopheles darlingi*
- Strategy to reduce host-seeking *Aedes aegypti*
- The collection, culture and characterization of the spotted fever agent: *Candidatus Rickettsia andeanae*
- Colonization of *Anopheles darlingi*
- Local capacitation and entomological studies in support of impregnated bednets use
- Mapping the current distribution and malaria infectivity of *Anopheles Darlingi* in the Amazon basin
- Development of phlebotomine sandfly surveillance
- Efficacy of three different regimens of Primaquine for the prevention of relapses of *Plasmodium vivax* malaria
- Investigation of severe and complicated malaria
- Malaria distribution
- Characterization of the infectious agent causing cutaneous Leishmaniasis in South America
- Infectivity of *Anopheles albimanus* with *Plasmodium vivax* for use in human clinical vaccine studies
- Investigating the impact of the interoceanic highway construction and disease transmission
- Influenza cohort (prospect studies)
- Implementation of Vigila (IVR/electronic-based disease surveillance system
- Diarrhea surveillance project in the military



★ •NAMRU-2 Jakarta (until June 10)

★ •Phnom Penh Field Lab

★ •Singapore Liaison Office

⦿ •Acute Febrile Illness Surveillance

● •Avian Influenza Surveillance

● •Shigellosis Morbidity

● •Drug Resistant Malaria

● •Syndromic Disease Surveillance

● •Influenza Like Illness Surveillance

Basic Tenets

- Close proximity of clinical medicine and basic/applied research can be a major driver of medical innovation
- Yesterday's "emergent issues" are still relevant. They are still the focus of S&T and advanced product development
 - **e. g., hemorrhage control**
- Emergent issues from the current battlefield will define the spectrum of R&D for many, many years to come
 - **e.g., blast TBI, PTSD, orthopedic injury from blast**
- Progress is spiral. What you start with is not what end up with
 - **Product development takes years. The final product may differ from the initial requirements due to technological advancements and the evolution of medical care.**
- Innovation from the bench is responsible for the majority of medical products
- Knowledge products (e.g., fleet guidance, changes in clinical practice, training or operations) are just a valid products

Examples of Translational Research from the NMRC Enterprise

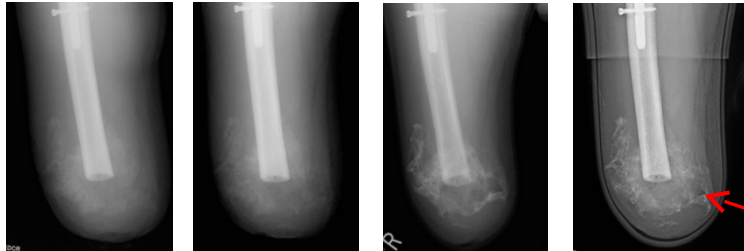


Navy Medicine Priority Research Topics

1. Traumatic Brain Injury and Psychological Health Treatment
2. Medical Systems Support for Maritime and Expeditionary Operations
3. Wound Management Throughout the Continuum of Care
 - (e.g.) predictive biomarkers of wound healing
 - (e.g.) Heterotopic ossifications
4. Hearing Restoration and Protection for Maritime, Surface and Air Support Personnel
5. Undersea (Diving and Submarine) Medicine

Examples, of many areas in the NMRC Enterprise, where basic and applied medical science converge that provide innovation to Navy medicine for the Warfighter

Heterotopic Ossifications



Heterotopic Ossification in High-Energy Wartime Extremity Injuries: Prevalence and Risk Factors

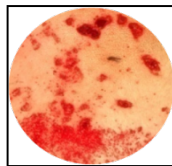
Jonathan Agner Forsberg, Joseph M. Pepek, Scott Wagner, Kevin Wilson, James Flint, Romney C. Andersen, Doug Tadaki, Frederick A. Gage, Alexander Stojadinovic and Eric A. Elster
J Bone Joint Surg Am. 2009;91:1084-1091. doi:10.2106/JBJS.H.00792

• Heterotopic Ossifications

- More prevalent in OIF/OEF casualties than in similar civilian trauma (60% vs. 20%)
- a problem for rehabilitation/prosthetics

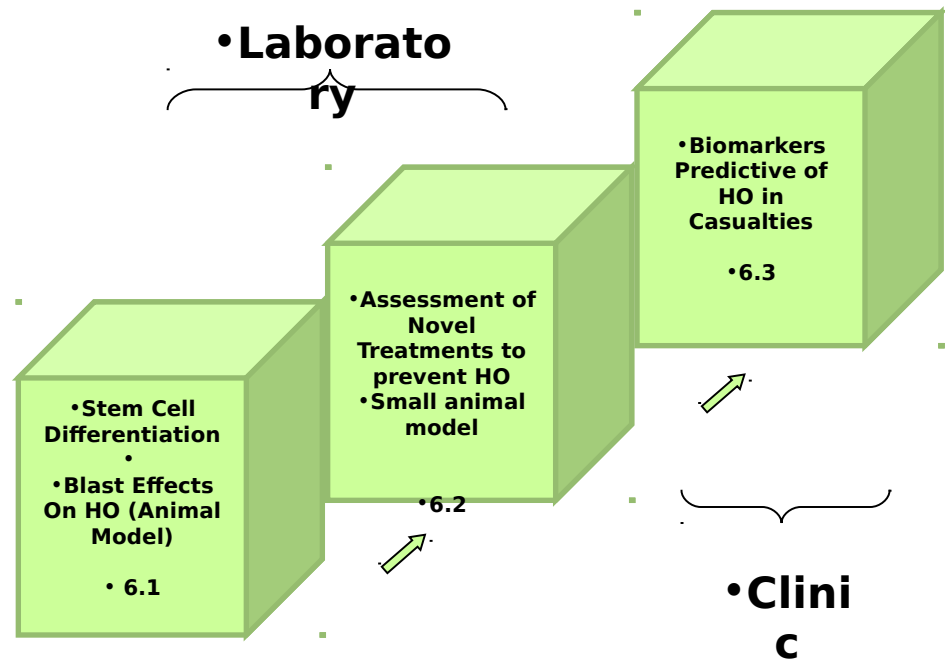
• Clinical Observation

• Basic Research



- Wound effluent promotes bone growth in culture

• Laboratory



• A basic/applied Research Program

Clinical scientists from NNMC and NMRC working collaboratively to detect emergent conditions from OIF/OEF. The collaboration facilitates the formation of a basic-applied research program involving MTF clinicians with NMRC researchers



- **Tissue biopsy**

- Serum

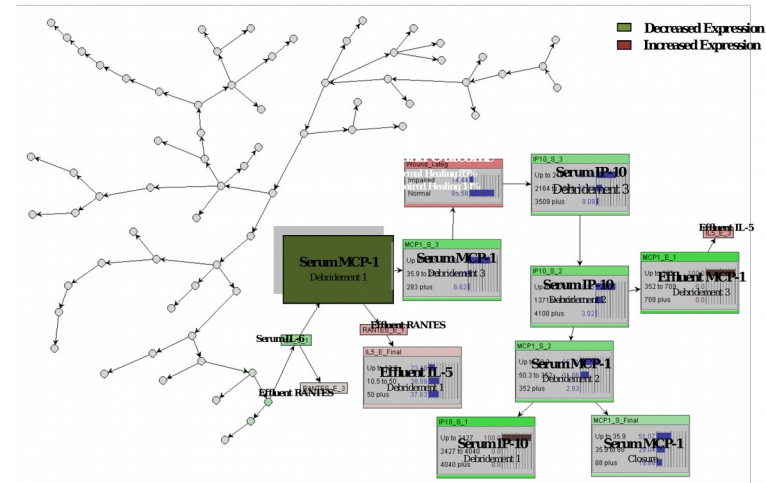
- **Wound Status**

- **Systemic Response**

- **Systems biology analysis** has demonstrated that biochemical markers predict wound outcome
- Predictive biomarkers of wounds may reduce the number of required surgical procedures (washouts in the OR)
- A prospective study of biomarkers to guide therapy is underway
 - An example where basic and applied medical science converge that provide innovation to Navy medicine for the Warfighter

Inflammatory Biomarkers in Combat Wound Healing

Jason S. Hawksworth, MD,*† Alexander Stojadinovic, MD,‡‡ Frederick A. Gage, ●●,*
Doug K. Tadaki, PhD,* Philip W. Perdue, MD,§ Jonathon Forsberg, MD,*‡¶ Thomas A. Davis, PhD,*
James R. Dunne, MD,§ John W. Denobile, MD,§ Trevor S. Brown, PhD,* and Eric A. Elster, MD*‡§



- **Probabilistic (Bayesian) Model**

Links to General Medical Education(GME)

- Residents recognized for excellence in research from the wound research program at NMRC/NNMC: (last 4 years)
 - **Jason Hawksworth**
 - **Jonathan Forsberg**
 - **Fred Obrien**
 - **Most of the residents have publications, many of them first authored in major journals**
 - **The Wound Research Program has on average, 4 surgical/orthopedic residents working in the laboratory at a time. It is a resident magnet.**

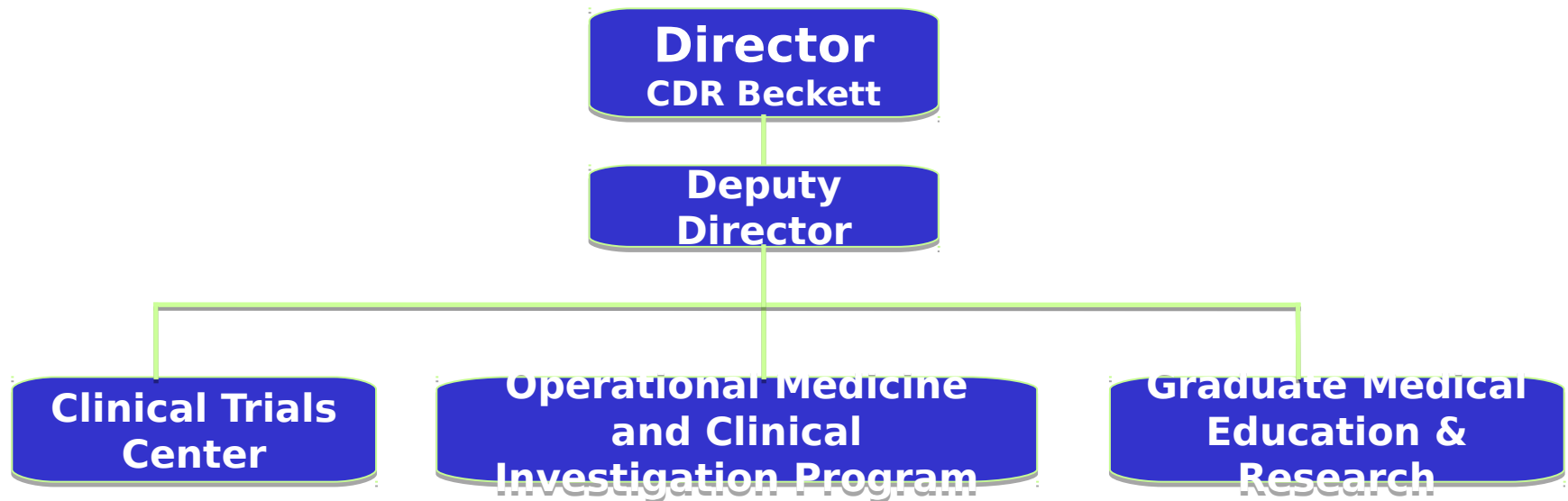
This “clinician centered” bench to bedside translational model took several years to construct and is the product of a collaboration between medical laboratories and MTFs.

Laboratory “Bench to Bedside” Ingredients

- Robust/Active/Funded Research Programs (a critical mass)
 - **Cadre of basic and applied scientists**
 - **Technical and administrative support (departmental/directorate)**
- Infrastructure (space)
- Billets for Clinicians (who split time between the laboratory and clinical practice)
- Research Support (institutional)
 - **Funds management**
 - **Agreements management**
- Research Mentorship
- Links to Clinical Departments (e.g., surgery)
 - **Residents (many spend a year doing research, long enough to complete a major project)**

Talented Clinicians are a necessary component but only a starting point to build a successful translational program. All of the elements listed above are key, particularly the research support components at a departmental and institutional level.

NMRC Translational Research Directorate/Office (TRED)



TRED Clinical Trials Center



- Hosts Outpatient Clinical Trials
 - **Supports the NMRC Enterprise**
 - **Supports MTF outpatient clinical trials on a space available basis**
 - **Supports USUHS clinical trials on a space available basis**
 - **Provides regulatory support for Phase 1 and 2 clinical trials**

TRED Operational Medicine and Clinical Investigation Program

- Bridges Navy R&D with Navy and Marine Corps operational needs
 - **Explores opportunities to provide operational support through R&D activities**
 - **Land and sea-based operational platforms**
- Integrates Navy R& D with MTF Clinical Investigation Programs
 - **Provides some administrative support for CIP**

TRED Graduate Medical Education and Research

- Integrates Navy R&D with the Navy Graduate Medical Education Program and USUHS
 - **Identifies opportunities for participation of medical students, residents and fellows in Navy R&D research activities**
 - **Coordinates the participation of USUHS/HPSP students in Navy R&D activities**
 - **Interacts with civilian medical education institutions for student participation in Navy R&D activities**

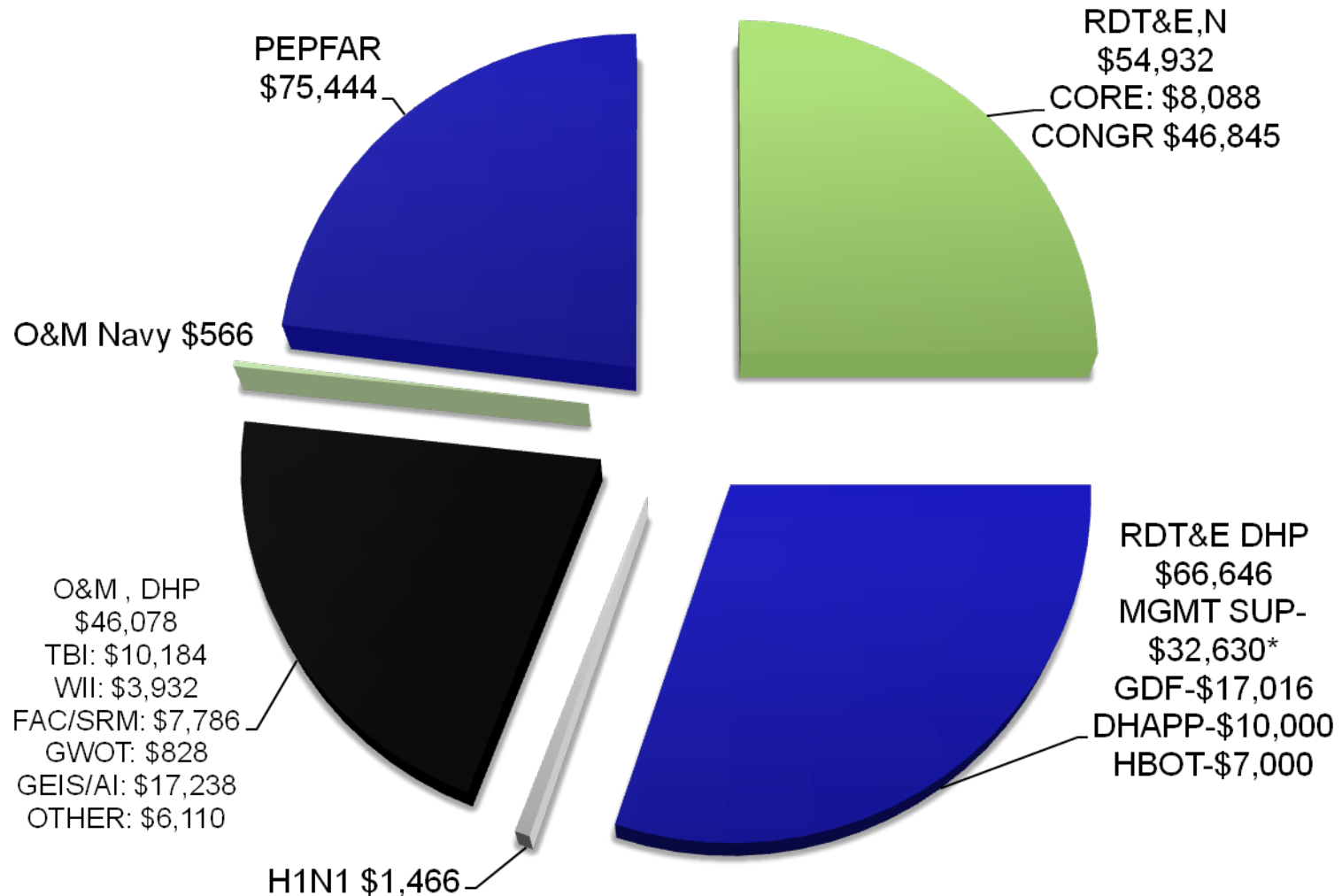
NMRC TRED

Next Steps

- Socialize with NMRC Directorates/Leadership
- Get buy-in from NMSC
- Discuss with BUMED/NMI to obtain support
 - **Financial Support**
- Form Steering Committee
 - **1 year term/Composition TBD**
 - **Strategic planning**
 - **Initial coordination of programs/resources**

• NMRC DIRECT FUNDING BY APPROPRIATION

FY10 Total
\$245,132 (\$K)



Clinical Research and the Clinical Investigations Program

- **Mission**

- To support and oversee conduct of relevant clinically relevant research projects that provide academic experience in clinical research while meeting the needs of Navy Medicine

- **Vision**

- Improving the quality of health care available to DoD operational personnel and other beneficiaries through clinical research.
- Generating an atmosphere of scientific inquiry as a means to assist in the appreciation of evidence based practices by clinical caregivers-in-training and thereby provide support for the accreditation of GME programs

Navy Program Management Governing Instructions

- **DoDI 6000.08**
 - CI Defined: An organized inquiry into clinical health problems for any condition of concern in providing healthcare to the beneficiaries of the military healthcare system including active duty personnel, dependents, and retired personnel
 - DoD Policy: CI is An Essential Component of Medical Care and Teaching: *Improving the quality of patient care* and supporting the graduate medical education (GME) programs
- **BUMEDINST 6000.12B (25JUN09)**
 - “Research is therefore an integral component supporting provision of premier state-of-the-art health care in the Navy”
 - BuMed Governance under M00MR
 - Includes Nursing, Dental and Allied Health
 - Aligns with Regional MTF Authority and Administration, DPE, Research Administration

Navy MTF Clinical Research

• IRBs at NNMC, NMCS, and NMCP(2)

• NAVY MED WEST

• NMC San Diego

- NH Bremerton
- NH Pendleton
- NH Lemoore
- NH Oak Harbor
- NH Okinawa
- NH 29 Palms
- NH Yokuska
- NH Guam
- NHCL Hawaii

• NAVY NCA

• NNMC Bethesda

- NHCL Annapolis
- NHCL Quantico

• NAVY MED EAST

• NMC Portsmouth

- NH Camp Lejeune
- NH Jacksonville
- NH Pensacola
- NOMI
- NH Beaufort
- NH Corpus Christi
- NH Naples
- NHCL Great Lakes

Trainees and Faculty Have Access to Research Experience at all 22 MTFs

MTF Clinical Research FTEs, Protocols and Publications²



CIP Program Metrics	<u>FY08</u>	<u>FY09</u>	<u>FY10</u>
Full Time Equivalents (FTEs)	16 (179)	21.5 (166)	21.5 (171)
Active Protocols (end of FY)	876 (2337)	800 (2566)	864 (2481)
Protocols/FTE support	55 (13)	37 (15)	40 (15)
New Protocols	428	321	212
Completions	• 504	• 397	• 148

CIP1 Funded Projects 2009-10

Investigator	Title	Award number	Approved funding
Lee, Rees L.	Assessment of Exhaled Oxidant	201013	\$ 56,700
DeMaio, M	Evaluation of Extremity fractures	20108	\$ 175,000
Rockwood, Jason	Insertional Trauma from Suprapatellar portal nails	201012	\$ 23,000
Mentler, Ellie	non-operative management of complicated appendicitis	20101	\$ 8,000
Mentler, Ellie	Wound infection Rates in Elective Colorectal Surgery	20103	\$ 8,000
Mentler, Ellie	Vacuum Associated Closure of the Abdominal fistula	20104	\$ 64,500
Goodrich, Jarod	Effects of Localized Hypothermia and negative pressure on wounds	201011	\$ 101,000
Manos, Gail H	Interpersonal Psychotherapy for depressed Spouses of Navy members	201015	\$ 26,000
Nezat, Gregory G.	Intraop IV lidocaine and post-op pain reduction	201010	\$ 32,600
		NMCP Total	\$ 494,800

CIP2 Funded Assets

GS

GS 13 Biostatistician	\$ 80,402	
GS 13 Grants Writer		\$ 80,402
½ FTE Librarian	\$ 18,352	
GS 9 IRB Administrator	\$ 46,625	
GS 9 OR Tech	\$ 46,625	
WG 4 Animal Tech		\$ 29,972
Subtotal	\$302,378	
28% Fringe	\$ 84,665	
SubTotal GS		\$387,043

Contract

Combat Casualty EMD		\$101,881
Research Nurse Peds		\$ 72,500
Research Coord Others		\$ 60,486
RA NHCL	\$ 29,999	
RA NH Jax	\$ 29,999	
RA OB Gyn	\$ 29,999	
RA ENT	\$ 29,999	
RA Ortho	\$ 29,999	
Contracting	\$ 11,545	

Subtotal Contracts

\$396,407	
Travel Increase	\$ 98,500
SG CIP2 Fund Total	\$881,950

Clinical Investigation Program GME

	NNMC**			NMCSD			NMCP			TOTAL		
	FY08	FY09	FY10	FY08	FY09	FY10	FY08	FY09	FY10	FY08	FY09	FY10
GME Programs	42	42	42	25	25	25	22	22	22	89	89	89 (154)
Number of Trainees	X	243	224	388	362	367	258	278	271	X	883	862 (1248) 70%
Protocols with Staff Pls/Als	199	711	139	429	284	274		163	158	469	586	571
Ratio*										54%	66%	66%
Protocols with Trainee Pls/Als	55	156	107	65	150	155	91	27	19	211	333	281
*Participation Ratio = staff or trainees on protocol/ total protocols includes co-duplications										19%	38%	33%

Clinical Research Accomplishments FY09

- **BUMED Headquarters Strategic Initiative Launched**
 - Report to SG/DSG
 - Deputy for MTF's assigned
 - CIP Instruction revised
 - Internal sources of funding identified
- **Communication: Jacksonville meeting**
 - BUMED, R&D, GME, and MTF communities together for first time
- **Coordination**
 - Data sharing, IRB agreements

FY09-10 Clinical Investigation Program Significant Research Findings

- NMCP: Anesthesia:** Intraoperative IV Lidocaine: Reduction of Post-Op Pain and Return of Bowel Function in Patients Undergoing Laparoscopic Abdominal and GYN Surgery
- NMCSD: ENT:** Comparative Non-linear Analysis of Local Skin Flap Design and Closure Using the Finite Element Method
- NMCSD: Surgery:** The Comparative Efficacy of Hemostatic Agents in Hemorrhagic Shock
- NMCSD: Ortho/Gait Lab:** Comparison of Gait Parameters Between ERTL and Standard Transtibial Amputations: Pilot study
- NMCP: Ortho:** Comparing irrigation solutions in a porcine open fracture model
- NMCP: Ortho:** Physical Performance Decrements in Military Personnel Wearing PPE
- NMCSD: PT/ENT:** Sensory substitution for rehabilitation of balance after TBI

Current Program Challenges

- Research Administrative Support:
 - **No uniform staffing/structure despite similar functionality**
 - **High staff turnover**
 - **Requirements based resourcing**
 - Modeled after civilian academic institutions
 - **Professional Science and Art**
 - **Resonating with Health Affairs Leadership**
- Data Quality
 - **Lack of Leverage**
 - Accounting platforms for collection and tracking metrics
- Dual Mission/Hidden costs
 - **Time (Residency hours/AHLTA/Production)**
 - **Experience/Mentoring**
 - **“Love” vs real reward for academic mission support**

“At Risk” GME Programs

Programs	Research Citations
Anesthesiology	(Scholarly Activity 2nd citation, 13 of 23 faculty lack publication). Although faculty scholarship has improved, 13 of the 23 faculty members had no publications during the last 5 years according to their curriculum vitae. Of the 10 faculty members who listed publications, only 6 faculty members had more than 2 publications. This situation represents a repeat citation. (PR.II.B.5.b)
Pulmonary/Crit Care	It is unclear that the fellows are actively involved in research. In the submitted program information forms only three fellows are listed with publications. The Review Committee expects more than half of the fellows to have publications and presentations. The majority of fellows must demonstrate evidence of recent research productivity through: (1) publication (manuscripts or abstracts) in peer-reviewed journals, or (2) abstracts presented at national specialty meeting (V.C.2.d).
Ophthalmology	The faculty does not demonstrate broad involvement in research and scholarly activity as measured by their aggregate publications and presentation. The lack of support for faculty research has an impact on resident research.
Pain Medicine	The faculty must establish and maintain an environment of inquiry and scholarship with an active research component. Some members of the faculty should also demonstrate scholarship by one or more to the following: 1) peer-reviewed funding; 2) publication of original research or review articles in peer-reviewed journals; or chapters in textbooks; 3) publication or presentation of case reports or clinical series at local, regional or national professional and scientific society meetings; or, 4) participation in national committees or educational organizations (Program Requirement II.B.f5). Review of the academic activities of the program director and faculty members indicates marginal productivity. The program should develop a plan to improve scholarly activity of the faculty.
Pediatrics	Faculty/Responsibilities/Scholarship/Active Research Program Requirement (PR) II.B.5. The Faculty must establish and maintain an environment of inquiry and scholarship with an active research component. The faculty does not demonstrate broad involvement in research and scholarly activity. The publications and grants listed in the PIF include few peer review funded projects and limited publications. Several physicians listed as grant recipients are no longer members of the faculty. Source: PIF page(s): 66-68

•FY10 Strategic Objectives

•Strategy / Governance

•Performance Gap: Current Performance v. Target

•Action Plan

EXEC SPONSOR	FY10 OBJECTIVES	PERFORMANCE METRICS	1 st QTR (30 Nov)	2nd QTR (15 Jan)	3 rd QTR (1 Jun)	4 th QTR	Target FY10	INITIATIVES ((as listed on the Strategic Communications Page (SCP), CPIMS and Boards/Working Groups))
Dr. Cheatham -Research Executive Report •Quadruple Aim: Learning and Growth • Research & Development & Clinical Investigative Program (RDCIP)	RDCIP1 - Produce required research products that preserve, protect, treat, rehabilitate, or enhance the performance of Navy and Marine Corps personnel and health care services. Increase products by 10%	RDCIP1a - Research Projects: Customer Needs, CURRENT SNAPSHOT	998 (59%)	1070 (63%)	1168 (69%)	1316 (78%)	1685	
	RDCIP2 - Engage in partnerships to enhance efficiencies and protect Navy Medicine pertinence in the research and academic communities. Sustain current level. * = R&D	RDCIP2a - Significant Collaborative Partners - CURRENT SNAPSHOT	324 (180 %)	340 (189 %)	508 (282 %)	540 (300 %)	180	

•FY10 Strategic Objectives

•Strategy / Governance

•Performance Gap: Current Performance v. Target

•Action Plan

EXEC SPONSOR	FY10 OBJECTIVES	PERFORMANCE METRICS	1 st QTR (30 Nov)	2nd QTR (15 Jan)	3 rd QTR (1 Jun)	4 th QTR	Target FY10	INITIATIVES (((as listed on the Strategic Communications Page (SCP), CPIMS and Boards/Working Groups)))
Dr. Cheatham -Research Executive •Quadruple Aim: Learning and Growth •Research & Development & Clinical Investigative Program (RDCIP)	RDCIP3 - Achieve & maintain a national & international reputation as a high quality high performance biomedical & military medicine research enterprise...ensuring recognition & accreditation of its clinical & academic programs.	RDCIP3a - Significant Publications, Technical Papers, Procedural Advancement, CUMULATIVE	458 (55%)	819 (98%)	1414 (170 %)	2014 (242%)	833	
	RDCIP4 - Create Common Operating Picture (COP) linking requirements with R&D/CI efforts in all venues - articulating the impact of outcomes on health care services	RDCIP4a - Common Operating Picture	---	---	---	---	TBD	SCP - Strategic Communications Plan for Research SCP - Coordinate Fleet Input Into Medical R&D SCP - Medical Capabilities Gap Analysis



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**By Congressional Mandate,
Navy is tasked with
conducting:**

- **Dental Disease Research**
- **Non-combat Dental
Emergency research**



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Opportunities in Navy Dental Research

- **There are 6 dental research billets**
- **All post graduate dental residents in training have the opportunity to and are encouraged to engage in research**



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Current Navy Dental Research Assets

- **Currently there are 2 DMD/PhDs and 1 in Training at UCSF.**
- **Dental Research Activities are Located at:**
 - **Naval Postgraduate Dental School (NPDS-NNMC), NMRC, NHRC, NAMRU-SA, USAMRMC, others**
- **Currently there are more than 80 ongoing residency related projects associated with the NPDS-NNMC and over 2 dozen projects being directed by staff among the other locations indicated above.**



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Dental Research Funding

- **The Dental Research Advisory Council Meets Annually to Determine Critical Gaps in Research Needs Reflected in Light of The SG's Strategic Priorities**
- **Research Directed to those Gaps are Prioritized by the Individual Research Commands**
- **Funding comes from Same Sources as Other Research:**
 - **Congressionally directed**
 - **ONR**
 - **DARPA**
 - **USAMRMC, etc**



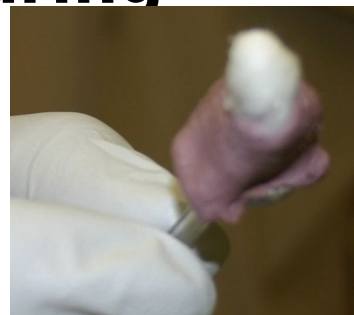
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Hearing Protection-Restoration

- Use of novel matrices for acoustic protection
- Use of dental materials for low cost customized & individualized hearing





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Undersea Medicine-Diving and Submarines

Transition of developed novel acoustic shielding materials to the fleet.



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The Current Command and Control for Navy Dental Research

- **Primary control is through the DRAC, in consultation with the Specialty Leader for Navy Dental Research.**

01/20/2011

*2011 Surgeon General's
Leadership Conference
Medicine Research & Development Center
BUMED M00MR*

• **CDR Ken Green**
• **BUMED M00MR5**
• **Kenneth.green2@med.navy.mil**
• **202.762.3177**

Nursing & Allied Health Sciences Research

Specialty Leaders for Nursing and Various Allied Health Sciences Research

- Serve only in an advisory role**
 - No direct authority or oversight**
 - Limited, to no interplay with Regional or Local MTF guidance**

Nursing & Allied Health Sciences Research

Funding, Managerial, and Portfolio Coordination - Oversight of Nursing and Allied Health Sciences Research

- **Semi-structured with minimal coordination of efforts**
 - **Commands may set some research priorities**
 - Internally supported
 - CIP funded
 - **“No cost” internally**
 - Encouraged due to minimal infrastructure and support impact
 - **Department research priorities**
 - Nursing directed command studies
 - **Self-directed/ researcher initiated**
 - TriService with alignment with TriService Nursing Research extramural funding priorities
 - Researcher interest driven

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